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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,613	11/14/2001	Pramod K. Srivastava	8449-183-999	9970

20583 7590 10/12/2006

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,613	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19, 21, 33-36, 39-42, 57-58, 63, 65, 77-80, 83-86, 101-102, 111-125, 132 and 149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19, 21, 33-36, 39-42, 57-58, 63, 65, 77-80, 83-86, 101-102, 111-125, 132 and 149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed June 26, 2006 in response to the Office Action of March 17, 2006 is acknowledged and has been entered. Claim 132 has been amended and claim 149 has been added in the Amendment filed June 26, 2006. To summarize the status of the claims in response to this and prior Amendments, claims 22, 25, 28, 31, 32, 45-48, 51-54, 60, 61, 66, 69, 72, 75, 76, 89-92, 95-98, 104, 105, 108, 110, 134, 136, 138, and 140-148 have been withdrawn, claims 1-18, 20, 23, 24, 26, 27, 29, 30, 37, 38, 43, 44, 49, 50, 55, 56, 59, 62, 64, 67, 68, 70, 71, 73, 74, 81, 82, 87, 88, 93, 94, 99, 100, 103, 106, 107, 109, 126-131, 133, 135, 137, and 139 have been cancelled. Claims 19, 21, 33-36, 39-42, 57-58, 63, 65, 77-80, 83-86, 101-102, 111-125, 132 and 149 are currently pending and are being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Objection/Rejection

Specification

3. The disclosure is objected to because of the following informalities:

The identifying data of all prior applications for which benefits are claimed should be provided in either the first sentence(s) of the specification or in an application data sheet. The priority data on page 1 should be updated to state that Application No. 09/489,218 is now U. S. Patent No. 6, 468, 540. See MPEP § 202.02.

Priority

4. Examiner has established a priority date of November 14, 2001 for claims 35,41,79, and 85 of the instantly claimed serial number 09/992,613 because the claims as currently constituted recite "Concanavalin A is affixed to agarose beads" and a review of the parent applications does not reveal the claimed limitation. Applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 35, 41, 79, and 85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of "Concanavalin A is affixed to agarose beads" in Claims 35, 41, 79, and 85 has no clear support in the specification and the claims as originally filed. Examiner's review of the specification did not reveal support for the newly added limitation. Applicant is invited to submit evidence pointing to page and line number in the specification wherein support for the newly added limitation can be found. The subject matter claimed in claims 35, 41, 79, and 85 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7 Claims 35, 41, 79, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava (US Patent No., 5,830,464, November 3, 1998 IDS), in further view of Griffen et al. (US Patent No., 5,756,291, May 26, 1998)

The claims are drawn to the immunogenic population of purified human stress protein-peptide complexes of claim 34, wherein the Concanavalin A is affixed to agarose beads. (Claim 35), the composition of claim 40, wherein the Concanavalin A is affixed to agarose beads. (Claim 41), the immunogenic population of purified human stress protein-peptide complexes of claim 78, wherein the Concanavalin A is affixed to agarose beads. (Claim 79), the composition of claim 84, wherein the Concanavalin A is affixed to agarose beads (Claim 85).

Srivastava teaches purification of gp96 protein peptide complexes with Concanavalin A Sepharose, see Column 13.

Srivastava does not teach purification of gp96 protein peptide complexes with Concanavalin A affixed to agarose beads.

Griffin et al. teach a purification method using Concanavalin A affixed to agarose beads, see Example 20, Column 117.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to purify gp96-peptide complexes by substituting Concanavalin A affixed to agarose for Concanavalin A Sepharose in the method of Srivastava because the use of Concanavalin A for purification of gp96 protein peptide complexes and the coupling of Concanavalin A to agarsose for purification methods were conventionally used in the art at the time of the invention. Since the methods were conventionally known at the time of the invention one would have had a reasonable expectation of success of using Concanavalin A affixed to agarose for purification of gp96 protein peptide complexes.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 19, 21, 33-36, 39-42, 57-58, 63, 65, 77-80, 83-86, 101-102, 111-125, 132 and 149 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 10, 11, 12, and 15 of U.S. Patent No. 6,468,540 B1 in view of Griffen et al. (US Patent No., 5,756,291, May 26, 1998). Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept and would have been obvious in view of the patented claims which have all of the characteristics of a composition/immunogenic population of purified stress protein peptide complexes obtained from tumor tissue wherein said complexes each comprise gp96 non-covalently associated with a peptide wherein the composition is purified. Although the claims are drawn to pet stress protein peptide complexes, given that the specification of U.S. Patent No. 6,468,540 B1 teaches that it is contemplated that the method described herein is particularly useful in the treatment of human cancer, see column 4 and 6. Given the specific suggestion to use human complexes in the treatment of human cancers, the substitution of human for pet complexes is *prima facie* obvious. Further, although the claims are drawn to pet complexes, the specification teaches that the term "immunogenic stress protein-peptide complex", as used herein, is understood to mean any complex which can be isolated from a mammalian tumor cell and comprises a stress protein non-covalently associated with a peptide, see column 4. Given the above, given the specific contemplation of complexes isolated from human tumors, it would have been prima facie obvious to substitute human stress protein/peptide complexes for the claimed pet stress protein/peptide complexes with a reasonable expectation of success. Although

the claims do not teach that the isolated stress protein-peptide complexes were purified with concanvalin A and eluted with a buffer comprising alpha-methyl mannoside the specification teaches the purification of gp96 using concanvalin A and eluted with a buffer comprising alpha-methyl mannoside, see column 10. Although the claims do not teach that the composition comprises the indicated adjuvants, the addition of all of the claimed adjuvants to the composition is taught in the specification, see column 11. Although the claims do not teach that the composition comprises a chemotherapeutic agent, the addition of all of chemotherapeutic agents to the composition is taught in the specification, see column 5. Although the claims do not teach that the composition comprises all of the indicated cytokines, the addition of all of the claimed cytokines to the composition is taught in the specification, see column 12. Although the claims do not teach that the composition comprises antibiotics or bioactive agents, the addition of antibiotics or bioactive agents to the composition is taught in the specification, see column 12. Although the claims do not teach that the composition comprises purified human stress protein-peptide complexes from all of the claimed cancers the specification teaches treatment all of the claimed cancers and metastases, see columns 5-7.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make the claimed the composition/immunogenic population of purified human stress protein peptide complexes obtained from human tumor tissue excised from a human wherein said complexes each comprise human gp96 non-covalently associated with a peptide wherein the composition is purified in combination with the products taught in the specification of U.S. Patent No. 6,468,540 B1 because the claimed compositions were well known in the art.

Each of these agents had been taught by the prior art to be effective in eliciting an antitumor immune response, thus the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to make a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill in the art would have reasonably expectation of success to elicit an antitumor immune response obtain with all of these agents since they had been demonstrated in the prior art to elicit an anti-tumor immune response.

U.S. Patent No. 6,468,540 B1does not teach purification of gp96 protein peptide complexes with Concanavalin A affixed to agarose beads.

Griffin et al. teach a purification method using Concanavalin A affixed to agarose beads, see Example 20, Column 117.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to purify gp96-peptide complexes by substituting Concanavalin A affixed to agarose for Concanavalin A Sepharose in the method of U.S. Patent No. 6,468,540 B1 because the use of Concanavalin A for purification of gp96 protein peptide complexes and the coupling of Concanavalin A to agarsose for purification methods were conventionally used in the art at the time of the invention. Since the methods were conventionally known at the time of the invention one would have had a reasonable expectation of success of using Concanavalin A affixed to agarose for purification of gp96 protein peptide complexes.

9. If applicant disagrees with any rejection set forth in this office action based on examiner's establishment of a priority date November 14, 2001 for claims 35,41,79, and 85 for the instantly claimed application serial number 09/992,613, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

10. All other objections and rejections recited in the Office Action of March 17, 2006 are withdrawn.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

SUSAN UNGAR, PH.D
PRIMARY EXAMINER